



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/210,995	12/15/98	LOOSMORE	1038-844MIS: ^{VB}

HM22/1014

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AIR MAIL

EXAMINER	
HINES, J	
ART UNIT	PAPER NUMBER
1641	7
DATE MAILED: 10/14/99	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/210,995

Applicant(s)

Loosmore et al.

Examiner
Ja-Na Hines

Group Art Unit
1641



☒ Responsive to communication(s) filed on Sep 13, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

_____ is/are pending in the application.

☒ Claim(s) 1-24

_____ is/are withdrawn from consideration.

Of the above, claim(s) _____

is/are allowed.

☐ Claim(s) _____

is/are rejected.

☒ Claim(s) 1-24

is/are objected to.

☐ Claim(s) _____

☐ Claims _____ are subject to restriction or election requirements.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Amendment Entry

1. The amendment filed September 13, 1999 has been entered. Claims 1 and 22 have been amended. Claims 1-24 are pending.

Drawings

2. The drawings are objected to because of the reasons set forth in the attached PTOL-948. Correction is required.

Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because Michel Klein did not date the declaration. However Examiner acknowledges the arrangements re-execution of the Declaration and is awaiting a properly executed Declaration.

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Claim Rejections - 35 USC § 112

4. Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants amendments.

Response to Arguments

5. Claims 1-5 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Barenkamp et al. (Mol. Microbio. 1996) has been withdrawn in view of applicants amendments.
6. Applicant's arguments filed September 13, 1999 have been fully considered but they are not persuasive. Applicants argues that Barenkamp et al., (WO 97/36,914) provides no suggestion that the High Molecular Weight (HMW) antigens can be used in conjunction with the recited antigens. However, Barenkamp et al., teaches that the HMW protein can be linked to an antigen, hapten or polysaccharide for eliciting an immune response to the antigen, hapten or polysaccharide (page 6 lines 2-5). Further, Barenkamp et al., teaches that targeting molecules used in combination immunogenic compositions can include fragments of bacterial toxins (page 6 lines 33-34). The immunogenic composition may also comprise at least one other immunogenic or immunostimulating material and at least one adjuvant, and teaches complexing additional components to the antigenic composition to enhance immune response including

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herpes simplex virus vaccine, pseudorabies virus vaccine, tetanus toxoid, poliomyelitis virus vaccine and hepatitis B virus antigen and others. Barenkamp et al., combined vaccines can contain material from various pathogens or from various strains of the same pathogen, or from combinations of various pathogens (page 22 lines 5-8). Barenkamp et al., specifically teaches that vaccines which contain antigenic material of several pathogens are combined vaccines and also belong to the present invention (page 22 lines 5-8). Therefore it would have been obvious at the time of applicant's invention to have an immunogenic composition to confer protection against *Haemophilus influenzae* comprising at least two different antigens, where one is a high molecular weight adhesin protein, HMW1 or HMW2, since Barenkamp et al. (WO 97/36,914), teaches that adhesin proteins are potentially important protective antigens which should comprise one component of a multi-component non-typeable *H. influenzae* vaccine and the other component as taught by Loosemore et al., is an analog of Hin47 because Hin47 is a non-proteolytic heat shock protein which substantially reduced in proteolytic activity and can be used as an antigen and be included in other immunogenic preparations.

7. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Both Barenkamp et al. (WO 97/36,914), and

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Loosemore et al., teach the use of adjuvants, the addition of other additional antigenic components and methods for immunizing a host against disease caused by an infection with *H. influenzae* comprising administration of the composition. Thus, applicants argument that because is no suggestion to combine a HMW protein and the Hin47 because neither protein is specifically recited is not persuasive. It would have been obvious at the time of applicant's invention to have an immunogenic composition which confers protection against *Haemophilus influenzae* comprising at least two different antigens, where at least one of the antigens is an adhesin and the other antigen is not an adhesin as taught by Barenkamp et al.(WO 97/36,914), in view of Loosemore et al., because Loosemore et al., teaches that adhesin proteins are potentially important protective antigens which should comprise other immunostimulating components; the Hin47 antigen is immunogenic because it stimulates an immune response, can confer protection against diseases caused by a bacterial pathogen, including *Haemophilus influenzae*; and may immunogenic composition may further comprise at least one other immunogenic or immunostimulating material.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

October 8, 1999

James C. Housel
10/12/99

JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER